

**** NOT FOR PUBLICATION ****

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
LUFKIN DIVISION

CANDELA CORPORATION and THE	§	
GENERAL HOSPITAL CORPORATION	§	
d/b/a MASSACHUSETTS GENERAL	§	
HOSPITAL,	§	Civil Action No. 9:06-CV-277
	§	
<i>Plaintiffs,</i>	§	
	§	JUDGE RON CLARK
v.	§	
	§	
PALOMAR MEDICAL TECHNOLOGIES,	§	
INC.,	§	
<i>Defendant.</i>	§	

**ORDER DENYING PLAINTIFFS' MOTION FOR JUDGMENT AS A MATTER OF
LAW AND GRANTING DEFENDANT'S MOTION FOR ENTRY OF JUDGMENT**

Plaintiff Candela Corporation¹ filed suit against Defendant Palomar Medical Technologies, Inc. on December 19, 2006, alleging infringement of United States Patent Nos. 5,810,801; 6,120,497; and 6,659,999. All of the patents relate to a method and apparatus for treating skin wrinkles using radiation.² Candela dropped its claims regarding the '497 and '999 patents before trial commenced. A jury verdict of no infringement, anticipation of claims 11-14 of the '801 patent by the New Star 130 Laser (Cool Touch), and obviousness of claims 11 and 14 of the '801 patent in light of four different combinations of prior art references was returned on October 7, 2008. Now before the court is Candela's renewed motion for judgment as a matter of

¹After suit was filed here, The General Hospital Corporation, d/b/a Massachusetts General Hospital a co-assignee of the patents in suit, was joined as a Plaintiff. *See* Doc. # 15.

²The background and technology of the '801, '497, and '999 patents are set out in the court's August 6, 2008 Claim Construction Order at p. 4 [Doc. # 168].

law on Palomar's invalidity defenses [Doc. # 249] and Palomar's motion for entry of judgment [Doc. # 253].

Because a jury could have found by clear and convincing evidence that the references asserted by Palomar rendered the asserted claims of the '801 patent invalid as anticipated and/or obvious, the court denies Candela's motion for judgment as a matter of law. The court grants Palomar's motion for entry of judgment and will enter its Final Judgment by a separate order.

I. Standard of Review

A motion for judgment as a matter of law ("JMOL") is granted when there is no legally sufficient evidentiary basis for a reasonable jury to find for the party on an issue on which that party has been fully heard. *Reeves v. Sanderson Plumbing*, 530 U.S. 133, 150, 120 S. Ct. 2097, 2110 (2000). In entertaining a motion for judgment as a matter of law, the court must review all of the evidence in the record. *Id.* In doing so, "the court must draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Id.* This is because "[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge." *Id.*

Thus, although the court should review the record as a whole, it must disregard all evidence favorable to the moving party that the jury is not required to believe. *Id.* That is, the court should give credence to the evidence favoring the non-movant as well as that "evidence supporting the moving party that is uncontradicted and unimpeached, at least to the extent that evidence comes from disinterested witnesses." *Id.*

II. Analysis

A. Candela's Renewed Motion for JMOL

Candela makes three arguments in its motion: (1) the references used by Palomar to establish obviousness and anticipation – specifically the ‘549 patent to Tankovich, the ‘749 patent to Eckhouse, and the NS130 Cool Touch – are not prior art because Candela was entitled to an invention date earlier than the patent application date; (2) the NS130 Cool Touch laser did not contain all the elements of claims 11-14 of the ‘801 patent; and (3) none of the obviousness combinations teach or enable “substantially unwrinkled skin.”

1. Whether the Tankovich, Eckhouse, and Cool Touch references were “prior art”

The ‘801 patent application was filed on February 5, 1997. It is undisputed that Tankovich, with a filing date of July 11, 1996, and Eckhouse, with a filing date of September 15, 1995, both pre-date the ‘801 patent application. There was trial testimony that indicated work on what eventually became the Cool Touch began as early as May 2, 1995³ and culminated with its first sale on October 31, 1996. Trial Tr. at p. 685, ll. 7-12. Candela argues, however, that it was entitled to a filing date that precedes the earliest of these references because the ‘801 patent had a

³Palomar witness, co-developer of the Cool Touch, and New Star Lasers CEO David Hennings testified that he actually began working on a nonablative wrinkle treatment in the early 1990s. Trial Tr. at p. 649, ll. 19-21. On May 12, 1994, Hennings met with individuals at the Beckman Laser Institute at the University of California Irvine to discuss combining Hennings’ collagen shrinkage and wrinkle treatment applications with the cooling technology used at UC Irvine. Trial Tr. at p. 654, l. 17 - p. 655, l. 3. Hennings testified that by the middle of 1994, some testing was going on using a 2.1 micron hominum laser. Trial Tr. at p. 669, l. 22 - p. 670, l. 7. It was not until May 2, 1995 that a 1.32 micron Nd:YAG laser was used. Trial Tr. at p. 677, l. 21 - p. 678, l. 20. According to Hennings, the 1.32 micron laser “basically worked great.” Trial Tr. at p. 678, l. 20. After this change in May 1995, Hennings testified that he engaged in discussions with the FDA, presented some of the clinical data at a December 1995 Symposium, and eventually made the first sale on October 31, 1996. Trial Tr. at p. 680, ll. 3-21, p. 685, ll. 7-10.

conception date of either October 21, 1992 or June 30, 1994 and was reduced to practice on January 10 and April 24, 1996.

Invalidity is an affirmative defense and, as the party asserting that the ‘801 patent was invalid, Palomar had the burden of persuasion to prove invalidity by clear and convincing evidence. *Technology Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008). Palomar had the initial burden of going forward (i.e., the burden of production) with evidence that there is prior art which renders the patent invalid, which in this case means prior to the 1997 application date of the ‘801 patent.

Once Palomar does so, the burden of production shifts to Candela to put forth evidence either that the prior art does not actually anticipate or that it is not prior art at all because the claims are entitled to an earlier invention date. *See id.* If Candela can do so, the burden of production shifts back to Palomar to convince the trier of fact that Candela is not entitled to the benefit of the earlier filing date. “‘Convince’ is the operative word, because if the court is not persuaded by clear and convincing evidence that [Palomar] is correct, [Palomar] has failed to carry its ultimate burden of persuasion, and its defense of invalidity. . . fails.” *Id.* at 1328.

Palomar attempted to demonstrate both that the Eckhouse and Tankovich patents, in combination with each other and with other references, rendered the ‘801 patent obvious under 35 U.S.C. § 103 and that the Cool Touch laser was a prior invention which invalidated the ‘801 patent under 35 U.S.C. § 102(g).

a. Tankovich and Eckhouse

Palomar satisfied its initial burden by demonstrating that these two prior patents had filing dates prior to that of the ‘801 patent (February 5, 1997), namely July 11, 1996 and

September 15, 1995, respectively. Candela must then put forth evidence demonstrating that the ‘801 patent claims are entitled to a priority date before the Tankovich and Eckhouse patent application dates.

“Conception is the touchstone of inventorship.” *Burroughs Wellcome Co. v. Barr Lab., Inc.*, 40 F.3d 1223, 1227-28 (Fed. Cir. 1994). It is the “formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.” *Hybridtech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986) (internal quotation omitted). An idea is considered to be “definite and permanent” when “one of ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.” *Burroughs Wellcome*, 40 F.3d 1223, 1228. The inventor must be able to “describe his invention with particularity.” *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1063 (Fed. Cir. 2005). This requires both (1) the idea of the invention’s structure and (2) possession of an operative method for making it. *Id.* Conception requires that the inventor “appreciate what he has invented.” *Id.* To demonstrate reduction to practice, a party must show that the inventor “(1) constructed an embodiment or performed a process that met all the limitations and (2) determined that the invention would work for its intended purpose.” *In re Omeprazole Patent Litigation*, 536 F.2d 1361, 1373 (Fed. Cir. 2008) (internal quotation omitted).

Where a party is the first to conceive but the second to reduce it to practice, that party must demonstrate “reasonable diligence toward reduction to practice from a date just prior to the other party’s conception to its reduction to practice.” *Mahurkar v. C.R. Bard*, 79 F.3d 1572, 1578 (Fed. Cir. 1996). The activities that tend to prove diligence “take a variety of forms” and are on a “continuum between, on the one hand, ongoing laboratory experimentation, and on the

other hand, pure money-raising activity that is entirely unrelated to practice” of the invention. *Scott v. Koyama*, 281 F.3d 1243, 1248 (Fed. Cir. 2002).

A party claiming his own prior inventorship, including whether he was diligent, must proffer evidence that corroborates his testimony. *Brown v. Barbacid*, 436 F.3d 1376, 1380 (Fed. Cir. 2006)⁴; *Sandt Tech., Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1350 (Fed. Cir. 2001). “Documentary or physical evidence that is made contemporaneously with the inventive process provides the most reliable proof that the inventor’s testimony has been corroborated.” *Id.* at 1350-51; *see also Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1373 (Fed. Cir. 1998). “Circumstantial evidence about the inventive process, alone, may also corroborate.” *Sandt Tech.*, 264 F.3d 1344, 1351.

Candela introduced evidence that Dr. Rox Anderson had the idea of removing wrinkles by denaturing dermal collagen as early as October 21, 1992, and that Dr. James Hsia described a method of treating wrinkles by using infrared radiation by June 30, 1994. *See* PX 140C, PX 7. Both Drs. Anderson and Hsia are named inventors on the ‘801 patent. PX 140C and PX 7 are the dated laboratory notes of Drs. Anderson and Hsia, respectively. Candela also provided testimony from Dr. Kathleen McMillian, another inventor of the ‘801 patent, that PX 7 was in Dr. Hsia’s

⁴The Federal Circuit in *Brown* collected cases regarding what may constitute diligence. *See, e.g., Lacotte v. Thomas*, 758 F.2d 611, 613 (Fed. Cir. 1985) (testimony of the inventor and his notebook records were adequately corroborated by his obtaining relevant supplies and the testimony of an associate); *Scott*, 281 F.3d 1243, 1248 (diligence was shown by efforts to locate a construction company capable of building a manufacturing plant for practicing the invented process on a large scale); *In re Jolley*, 308 F.3d 1217, 1329 (Fed. Cir. 2002) (where diligence was shown by activity to obtain necessary supplies and laboratory glassware and by testing of related materials).

handwriting⁵ and that his notes matched her recollection of the work done during that period, as well as from Dr. Anderson, which corroborated his notes. Trial Tr. at p. 258, l.20 - p. 260, l.8; p. 321, l.21 - p. 324, l.22; p. 325, l.21 - p.327, l.23; p. 338, l.25 - p.341, l.11.

At the same time, Dr. Anderson's single page of notes from October 21, 1992 is not overly specific. It merely states that he had the idea of a wrinkle remover based on collagen denaturation, where the dermal temperature would be heated to 65-70 degrees C° while the skin was stretched along the wrinkle and the only fibers denaturated were those which crossed the wrinkle. PX 140C. Dr. Hsia's notes are more extensive, and discuss treating a wrinkle by heating the dermal collagen about 1 millimeter below the skin surface to about 70 degrees Celsius using radiation with a wavelength between 1.3 and 1.85 microns. PX 7. Dr. Hsia's notes also discuss the idea of cooling the skin in order to avoid collateral damage. Like Dr. Anderson's, however, they are more theoretical than specific. The fact that Candela alleged two different conception dates at all indicates an uncertainty as to exactly when the invention was conceived.

With respect to reduction to practice, Candela produced PX 13, a March 1996 progress report which described the first live pig testing on January 10, 1996, and PX 472, a May 1996 review of the March 1996 progress meeting which further described pig testing and the first human test on April 24, 1996, as well as testimony from Dr. Anderson and the final '801 patent co-inventor, Dr. E. Victor Ross, on these points. Trial Tr. at p. 349, l.12 - p. 352, l.22; p. 353, ll. 1-7; p. 1045, ll.4-17; p. 1055, l.3 - p. 1056, l.1.

⁵Dr. Hsia did not testify live at trial. A short portion of his videotaped deposition testimony was shown by Palomar.

Candela also produced some evidence of diligence. Dr. Anderson testified that he spent some time in late 1992 and early 1993 looking into different laser options and deciding whether his idea was worth pursuing, Trial Tr. at p. 328, l.14 - p. 329, l.5, and put together a team and funding during the same period, Trial Tr. at p. 329, l.8 - p. 330, l.11. Dr. McMillan testified that she was working on calculations relating to the Monte Carlo beam propagation method described in Dr. Hsia's June 1994 notes during the "early to mid 1990s," Trial Tr. at p. 260, ll. 9-13, and that during 1995, she worked on a wrinkle treatment project using a 1.5 micron Er:Glass laser, Trial Tr. at p. 264, l.19 - p. 267, l.11; p. 269, l.6 - p. 270, l.12 (in vitro testing on pig skin with laser); p. 270, l.13 - p. 274, l.2 (preparations made for live pig study and performing study in December 1995 at Mass General). Dr. Anderson also testified regarding a human test Dr. Hsia had performed on himself on April 24, 1996, PX 476, Trial Tr. at p. 351, l.21 - p. 353, l.7, and that he had contacted the patent and licensing office at Mass General on October 12, 1996. PX 140B, Trial Tr. at p. 353, l.11 - p. 356, l.5.

Regardless of the notes of Drs. Anderson and Hsia, the jury was entitled to find that Palomar had proved by clear and convincing evidence that they did not reduce the invention to practice in January or April 1996, or that they did not exercise diligence in reducing the invention to practice. Dr. Anderson's notes mention that one "could cool the [skin] surface," but does not disclose the cooling system which minimizes injury element present in asserted claims 11-14, nor the exact area which would be cooled. Claims 11-14 are apparatus claims; Dr. Anderson's notes discuss, at best, a method of reducing wrinkles with some of the elements found in claims 11-14. Dr. Hsia's notes are more specific, but the jury still could have found that they did not contain every limitation of claims 11-14.

While Candela produced PX 13, PX 472, and some trial testimony on experiments done in January and April 1996, the exhibits and testimony do not compel the conclusion that the apparatus used to obtain these results was, in fact, what is covered by claims 11-14. PX 472 and 13 are both results-oriented and give little detail about the apparatus used to obtain the results. PX 13 also states that, unlike the '801 patent claims which use a cooling system to "minimize injury to the epidermal region," post-experiment biopsies on December 20, 1995 and January 10, 1996 revealed "focal epidermal damage" (December 20) and "epidermal and deep dermal damage" (January 10) for certain pulse energies and powers. The March 12, 1996 progress report, PX 13, further states that in the experiments conducted to date, the inventors had been "unable to find the perfect energy/power combination for selective mild dermal damage with epidermal damage[.]"

There was also evidence at trial that live pig skin is not an adequate substitute for wrinkled human skin. PX 20, which was written by '801 patent co-inventor Dr. McMillan, is a project report which states that "while there is a good model for human skin (pig skin) there is not a good animal model for wrinkled human skin, and so a substantial degree of risk will remain with the project until clinical studies can be performed." Candela's expert, Dr. Thomas Milner, also testified that he considered experiments on pig skin to be a waste of time, Trial Tr. at p. 1414, l.6 - p. 1415, l.22, as did Palomar's expert, Dr. Lawrence Bass. Tr. at p. 1322, l.5 - p.1323, l.4. With respect to the single human test on Dr. Hsia on April 24, 1996, the only document which mentioned the test, PX 472, notes only that the test took place and a laser with a certain number of pulses (24), frequency (4 Hz), and fluence (0.2 J/pulse). There is no mention of the

details of this apparatus, nor whether the test performed produced substantially unwrinkled skin as is required in claims 11-14 of the '801 patent.

Candela was required to present evidence of diligence on the part of the inventors from the time the second entity enters the field of invention through the date of reduction to practice. Depending on whether the jury believed there was actual reduction to practice on either January 10 or April 24, 1996 or no constructive reduction to practice until the '801 patent filing date, and which reference they were considering, the critical period for diligence could be any one of several possibilities between September 15, 1995 (the date the Eckhouse patent, the earlier of the two references, was filed) and February 5, 1997 (the date the '801 patent was filed). Candela pointed to several events that happened during this time period, namely one shipping order from December 18, 1995 for an Er:Glass laser and dye for the first live pig tests (PX 726), live pig testing in December 1995 through May 1996 (PX 13, 472), one instance of live human testing in April 1996 (PX 472), and submission of an invention disclosure to Mass General in October 1996 (PX 140B). However, there are substantial gaps of time during which Candela could not point to any activities. From May 1996 through February 1997, for example, the only action was Dr. Anderson's October 22 letter to Mass General.

Based on this record, a jury was entitled to find by clear and convincing evidence that Palomar demonstrated that Candela is not entitled to the benefit of an earlier filing date because Candela did not actually reduce the idea to practice first or exercise diligence and that, as a result, the Tankovich and Eckhouse patents were prior art.

b. NS130 Cool Touch laser

The parties dispute the category of potential prior art under which the Cool Touch should be considered. Candela argues that only prior use or knowledge under 35 U.S.C. § 102(a) is applicable, while Palomar suggests the Cool Touch is also a prior invention under Section 102(g)(2). Candela contends that this court rejected a Section 102(g) defense on the fourth day of trial after being supplied with Palomar's preliminary list of the references and combinations it intended to rely on.⁶ However, what was presented at that time as a potential prior art reference was the "work of David Hennings, Bruce Sand, and others for or on behalf of New Star Lasers with supporting testimony and documents." After Palomar had put on its invalidity case and the issue had been discussed at the charge conference, the court submitted to the jury a description of both categories of art (prior use or knowledge and prior invention), as well as the "New Star 130 Laser (Cool Touch)" as a potential item of prior art for anticipation purposes. Despite Candela's argument to the contrary, the court did not reject Palomar's attempt to rely on a Section 102(g) defense with respect to the Cool Touch at trial.

David Hennings testified at trial that he began working on methods for nonablative wrinkle treatment with Dr. Bruce Sand in 1992 or 1993. Trial Tr. at p. 641, ll. 8-11; p. 649, ll.

⁶ "[T]he idea that this work by Mr. Hennings [was anticipatory] – it might be part of an obviousness defense. . . every single part of this was not done by Mr. Hennings, based on his testimony. And we've already gone over the fact that your expert did not properly – or his testimony is going to be very limited as to what he put in his report. But we'll see what kind of – what you put on." Trial Tr. at p. 1063, l.23 - p. 1064, l.7. At the Final Pre-Trial Conference, the court stated that Palomar's invalidity expert, Dr. Bass, would be limited to his specific disclosures on the Hennings/Sand notebooks and documents, which "isn't much." FPT Tr. at p. 19, l.19 - p. 20, l.20.

19-25. In May 1994, Mr. Hennings met with Dr. Stuart Nelson and Dr. Thomas Milner⁷ of the Beckman Laser Institute at the University of California Irvine to discuss combining the collagen shrinkage and wrinkle treatment applications he and Dr. Sand had been working on with Beckman's new dynamic cooling technology. DX 466, Trial Tr. at p. 653, l.18 - p. 655, l.19.

Mr. Hennings also testified that prior to May 1994, he worked with a number of different mid-infrared lasers⁸ at his company, Sunrise Technologies, on the collagen shrinkage project. Trial Tr. at p. 655, l.20 - p. 656, l.8. After the May 1994 meeting at Beckman, Mr. Hennings stated that they started "working together at a frantic pace. . .to actually get things done." Trial Tr. at p. 658, ll.18-23. Mr. Hennings discussed Dr. Milner's modeling of the possible effects of combining the laser and the cooling technology to target the mid-dermal region, Trial Tr. at p. 659, ll.1-8; p. 660, ll. 2-14, and referred to a research program schedule for the collagen shrinkage application in dermatology created in July 1994 and planning a schedule through late 1995 which included writing protocols, filing preliminary patent applications if possible, performing animal studies, presenting data at conferences, and recruiting a corporate partner.⁹ Trial Tr. at p. 661, ll.9-21; DX 471; *see also* DX 473 (notes on a conversation with Dr. Milner relating to using certain lasers and exposure parameters in August 1994); Trial Tr. at p. 667, l.8 - p. 668, l.21 (Mr. Hennings testimony regarding some experiments Dr. Milner had done with the New Star laser on collagen); DX 474 (August 1994 letter from Beckman regarding performing

⁷Dr. Milner was Candela's infringement and invalidity expert at trial.

⁸Mr. Hennings defined "mid infrared" as between 1 and 3 microns (1000-3000 nanometers). Trial Tr. at p. 656, ll. 12-23.

⁹By this time, Mr. Hennings had started a new company, New Star Lasers, which eventually marketed the NS130 Cool Touch.

studies to determine if collagen shrinking using a 2.1 micron holmium laser was possible); DX 477 (December 1994 memo from Dr. Milner with thermal modeling using three different lasers including a 2.1 micron holmium YAG laser); DX 478 (draft of a patent application dated January 9, 1995); DX 533 (Mr. Hennings' lab notebooks dated March 17, 1995 [idea for combining laser with a non-contact delivery system and Beckman's cooling technology] and May 2, 1995 [using a 1.32 micron Nd:YAG laser and noting that it "worked great"]); DX 493 (program from a December 1995 symposium where Mr. Hennings and Dr. Sand presented some clinical and modeling data); DX 494 (abstract of symposium presentation). The first sale of the 1.32 micron NS130 laser took place on October 31, 1996. DX 520.

As discussed above, based on the evidence in the record, the jury could have found by clear and convincing evidence that Candela was not entitled to a filing date earlier than the patent application. Palomar put forth sufficient evidence that the Cool Touch was first sold in October 1996, more than three months before the '801 application was filed in February 1997, and could therefore be considered as prior art.

2. Whether Palomar submitted sufficient evidence for the jury to find that the NS130 anticipated the '801 patent

Palomar produced evidence at trial which, if believed, demonstrated that each limitation of claims 11-14 was anticipated by the Cool Touch. For example, Palomar introduced the deposition testimony of '801 patent co-inventor Dr. James Hsia, as well as DX 553 and 554, at trial. DX 553 is a June 9, 2003 letter from Candela to the FDA that submitted supplemental information for a 510(k) submission. In this letter, Candela states that "the mode of action for wrinkle reduction is the same as that shown for Cool Touch in the treatment of wrinkles. . .and

the Smoothbeam Laser in the treatment of periorbital wrinkles and the treatment of atrophic acne scars.” In the 510(k) submission itself, DX 554, Candela indicated that the Cool Touch was a “predicate device” for the Smoothbeam Laser System and states the following:

The indication for use of the treatment of facial wrinkles is based on substantial equivalence to the Cool Touch Laser. . . Additionally, the Candela Smoothbeam Laser utilizes the identical or similar operating principles, matches key design aspects, including same spot size, same of similar wavelength and same maximum delivered power as the predicate devices. On this basis, Candela believes that the Candela Smoothbeam Laser System is substantially equivalent to the predicate devices for the same indications of use.

DX 554, at p. CANTX2152016. Candela’s Smoothbeam device embodies the claims of the ‘801 patent. Dr. Hsia also testified that Candela told the FDA that “both lasers protect the epidermis and produce injury in the dermis and both lasers produce clinical improvement based on one or more of the following: dermal collagen contraction, fibroblast stimulation, and prolonged neocollagenesis. Trial Tr. at p. 1204, ll. 19-24.

Candela focuses its argument on three claim elements which it contends the Cool Touch laser did not meet: the “cooling system”; “wherein the beam of radiation causes thermal injury to the targeted dermal region sufficient to elicit a healing response”; and “produces substantially unwrinkled skin.” At trial, Palomar produced DX 478, which was a first draft of a patent application dated January 9, 1995 and is similar to parts of the April 1996 PCT Application filed by Mr. Hennings entitled “Improved Method and Device for Laser Induced Shrinking of Collagen.” See DX 500. The cover letter of DX 478 indicates that it was sent from Dr. Sand to Mr. Hennings. Mr. Hennings testified at trial that the application was an attempt to “specifically patent the things we’ve been working on” up to that point. Trial Tr. at p. 674, l. 23 - p. 675, l. 13. This work ultimately culminated in the April 1996 PCT Application and the Cool Touch laser.

With respect to “wherein the beam of radiation causes thermal injury,”¹⁰ the application discloses using a laser to “elevate the temperature of the target tissue to T_s for collagen shrinkage; a temperature below that which results in protein denaturation and trauma.” DX 478 at 100856; *see also* DX 494 at 101399 (December 1995 presentation of Dr. Sand at Cosmetic Eyelid Rejuvenation Symposium); PX 500 at 5874. For “sufficient to elicit a healing response,”¹¹ the 1995 patent specification discusses the components of the extracellular matrices of connective tissues like skin, namely collagen, elastin, and glycosaminoglycans, and notes that the “net accumulation of connective tissue is, thus, dependent upon the precise balance between the synthesis and the degradation of the connective tissue components.” DX 478 at 100854. Further, the specification states that removing or altering glycosaminoglycans “considerably weakens the connective tissue integrity and influences the thermal transformation temperature.” *Id.*; *see also* DX 500 at 5873.

For “substantially unwrinkled skin,”¹² *see* DX 494 at 01399 (discussing the laser developed by New Star and stating that it produces a “smooth surface”); DX 500 at p. 5872 (stating that the laser method of shrinking collagen “remov[ed] wrinkles”); DX 478 at 1000856 (“wrinkle removal”). Finally, with respect to the cooling system, *see* Trial Tr. at p. 660, l. 15 - p.

¹⁰The court construed the term “causing thermal injury” as “injury to collagen, caused by heating, which partially denatures the collagen.” Doc. # 168, at p. 15. The parties agreed at the *Markman* that a “beam of radiation” means just that: “a beam of radiation.” *Id.* at p. 6.

¹¹The court construed the term “sufficient to elicit a healing response” as “sufficient to activate fibroblasts, which deposit increased amounts of extracellular matrix constituents (i.e., collagen and glycosaminoglycans), that leads to the remodeling of said extracellular matrix.” Doc. # 168, at p. 23.

¹²The court construed this term to mean “skin from which the wrinkles have been considerably or largely reduced or removed.” Doc. # 168, at p. 21.

661, l. 8 (testimony of David Hennings); DX 478 at 1000856-1000857 (discussing a cooling system to reduce temperature in the epidermis while minimizing surface thermal damage); DX 500 at 5876. In short, there was sufficient evidence in the record for the jury to find, by clear and convincing evidence, that David Hennings' work, as embodied in the Cool Touch laser, anticipated claims 11-14 of the '801 patent.

3. *Whether obviousness combinations taught or enabled "substantially unwrinkled skin"*¹³

Even assuming no reasonable jury could have found that the Cool Touch laser anticipated claims 11-14 of the '801 patent, the court concludes that the jury could have found that the asserted combinations of art rendered claims 11 and 14 obvious. The court submitted four different combinations of art¹⁴ to the jury, and the jury found that claims 11 and 14 were obvious in light of all four.

¹³Palomar suggests that Candela did not timely raise this issue at trial because, rather than raising in its motion for JMOL what particular elements were missing from the obviousness combinations, Candela moved for JMOL generally on the grounds that the references did not teach the claimed subject matter. Trial Tr. at p. 1428, ll. 3-15; p. 1439, ll. 2-8. Fed. R. Civ. P. 50(a) requires only that a pre-verdict motion for JMOL "specify the judgment sought and the law and facts that entitle the movant to the judgment." Candela specified what it requested (JMOL on obviousness) and the law and facts entitling it to judgment (that the references did not teach the claimed subject matter and therefore did not render the asserted claims obvious). The court did not request more detail at that time, and considers Candela's oral motion sufficient to preserve its rights under Rule 50.

¹⁴These four combinations were: (1) United States Patent Nos. 5,964,749 to Eckhouse and 5,897,549 to Tankovich; (2) the Eckhouse and Tankovich patents, along with United States Patent No. 5,755,753 to Knowlton; (3) the Eckhouse and Tankovich patents, along with "Wrinkles shrivel under fire from pulsed lasers" in New Scientist by Kincade; and (4) the Tankovich and Knowlton patents, along with United States Patent No. 5,814,040 to Nelson. See Doc. # 248, at p. 5.

For the reasons discussed above, there was sufficient evidence for the jury to find that the Tankovich and Eckhouse patents were prior art. However, Candela also argues that the obviousness combinations do not teach “substantially unwrinkled skin” because neither the Tankovich or Eckhouse patents either discuss “removing” wrinkles nor enable the person of ordinary skill in the art to practice this claim element. The Eckhouse patent, which was submitted to the jury as DX 393, states that the invention “relates to a new method and apparatus of removing wrinkles and rejuvenating skin” and that the claimed apparatus is “very useful for wrinkle removal and skin rejuvenation.” Col. 3, ll. 22-23; col. 4, ll. 16-17. Palomar’s expert, Dr. Bass, testified that a person of ordinary skill in the art would have understood these statements to disclose the claim element of “substantially unwrinkled skin.” Trial Tr. at p. 1327, ll. 3-8. As noted above, the court construed this term as “skin from which the wrinkles have been considerably or largely reduced or removed.” Doc. # 168, at p. 21.

Although not as explicit as Eckhouse, the Tankovich and Knowlton patents also contain disclosures from which the jury could have found the “substantially unwrinkled skin” element satisfied. The Tankovich patent, which was submitted to the jury as DX 398, contains the following disclosure: “transforming relatively deep formations of undesirable sub-surface tissue in a living being.” Sub-surface tissue is defined as including mechanically damaged dermis collagen, an example of which is “tissue mechanically damaged by frequent or continuous muscular contraction (e.g., lines in the forehead region of the face).” Col. 3, ll. 16-18; ll. 37-40. Dr. Bass testified at trial that this disclosure teaches treating wrinkles to “produce substantially unwrinkled skin” as required by the asserted claims. Trial Tr. at p. 1331, l. 25 - p. 1332, l. 10. Similarly, the Knowlton patent, submitted to the jury as DX 750, teaches that “Partial

denaturization [sic] of collagen tissue results in a shrinkage of the collagen and provides a tightening effect on the overlaying skin. . . There has been a large market for tightening the skin in order to reduce aging effects. . . .” Col. 2, ll. 5-7; col. 1, ll. 41-43.

Based on these disclosures and Dr. Bass’s testimony, there was sufficient evidence for the jury to conclude that the Eckhouse, Tankovich, and/or Knowlton patents disclosed the limitation in claims 11 and 14 of the ‘801 patent that “substantially unwrinkled skin” be produced. Candela’s motion for JMOL does not assert that any other claim limitation is not met by the art combinations submitted to the jury.

B. Palomar’s Motion for Entry of Judgment

A party may request the court enter judgment under Fed. R. Civ. P. 56(d). Having denied Candela’s motions for JMOL, the court grants Palomar’s motion and will enter judgment by separate order.

IT IS THEREFORE ORDERED that Plaintiffs Candela Corporation and The General Hospital Corporation, d/b/a Massachusetts General Hospital’s Renewed Motion for Judgment as a Matter of Law [Doc. # 249] is DENIED.

IT IS FURTHER ORDERED that Defendant Palomar Medical Technologies, Inc.’s Motion for Entry of Judgment [Doc. # 253] is GRANTED.

So **ORDERED** and **SIGNED** this **29** day of **December, 2008**.



Ron Clark, United States District Judge